PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Krivitski & Drost	Atty. Docket:	86017.000010
Serial No.:	09/419,849	Examiner:	
Filed:	October 19, 1999	Art Unit:	

Title: METHOD AND APPARATUS TO MEASURE BLOOD FLOW BY AN INTRODUCED VOLUME CHANGE

Declaration Under 37 C.F.R. §102(d)

Commissioner of Patents and
Trademarks
Washington, D.C. 20231

Sir:

I, Cornelis J. Drost, hereby declare as follows:

1. I am a co-inventor of the present application. I am familiar with technology encompassed by the present application.

2. In-Line Diagnostics, d/b/a Crit-Line, is now actually marketing and has used a device and associated method under the name Transcutaneous Access Blood Flow or TQa. Evidence of such device being on the market and use is set forth herein.

3. The TQa was demonstrated at a booth during the 2000 American Society of Nephrology Meeting in Toronto, Canada, by Inline Diagnostics, Incorporation. Two abstracts presented by In-Line Diagnostics at the Toronto meeting and are attached as Exhibit A.

4. In a news release dated December 22, 2000, In-Line Diagnostics announced the Transcutaneous Access Flow device indicated for the transcutaneous estimation of access blood flow had received FDA 510(k) clearance for sale in the United States. A copy of the In-Line Diagnostics press release is attached as Exhibit B.

5. As shown in Exhibit B, the December 22, 2000 press release by Inline Diagnostics states "The TQa technology provides the real-time determination of vascular access blood flow rate based on relative changes in hematocrit (red cell

volume). This new technique eliminates the need for dialysis line reversal... The Crit-Line is a non-invasive stand-alone blood monitoring system employing proprietary photooptical technology which enables the continuous real time measurement of vital whole blood parameters, such as hematocrit percent change in blood volume and oxygen saturation...As a complement to the Crit-Line, the TQa will revolutionize the access blood flow market due to its minimal test time, accuracy, ease of use, and elimination of line reversal requirements."

6. A true and correct copy of the 510(k) No. K001763 Summary dated December 22, 2000 for the TQa is attached as Exhibit C.

7. Exhibit C, the 510(k) Summary states in part "Between April 22, 2000 and June 1, 2000, 72 data points were clinically gathered on 59 patients comparing CLM III_{TQa}'s transcutaneous readings to the HD01 monitor." [Exhibit C, Page 6]

8. The TQa is being currently marketed by In-Line Diagnostics as advertised in the *Nephrology News & Issues*, of November 2000. A copy of this advertisement is attached as Exhibit D.

9. Therefore, the TQa device or product is actually on the market and the method has been, and is believed to be continually used.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Cornelis J. Drost

Dated: Feb-5, 2001